Paper No. 21

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte WALTER ELGER, PEKKA LAHTEENMAKI, MATTI LEHTINEN, GUDRUN REDDERSEN, HOLGER ZIMMERMANN, MICHAEL OETTEL, and SIGFRID SCHWARZ

Appeal No. 2003-2087
Application No. 09/744,574

ON BRIEF

Before WINTERS, ADAMS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 8-17, all of the claims remaining. Claim 8 is representative and reads as follows:

8. A method of achieving hormone replacement therapy in a woman comprising intermittently orally administering an estrogen sulfamate at a dosage of 20-300 µg/day in intervals of 2 or 3 days; 0.5-5.0 mg/day in intervals of 5-10 days; or 2.0-20 mg/day in intervals of 20-40 days.

The examiner relies on the following references:

Gale et al. (Gale)	5,314,694	May 24, 1994
Siemann	WO 96/05216	Feb. 22, 1996

Claims 8-17 stand provisionally rejected for obviousness-type double patenting over claims 23 and 24 of application 09/755,429. Claims 8-17 also stand rejected under 35 U.S.C. § 103 as obvious in view of Siemann and Gale.

We affirm the double patenting rejection and reverse the obviousness rejection.

Background

The specification discloses the use of "biogenic estrogen sulfamates" such as estradiol sulfamate in hormone replacement therapy. See, e.g., pages 1 and 11. The estrogen sulfamates are disclosed to be prodrugs that are converted into the bioactive species by cleavage of the sulfamate group. Administration of the sulfamate prodrug is disclosed to have the advantage that "[b]y slow release from the sulfamate prod[r]ug in humans according to the invention, very uniform, exactly defined levels of natural estrogens can be built up in the blood." Page 13. "Slow release of natural estrogens, in connection with a high oral bio-availability of the steroid portion of the administered estradiol sulfamate according to the invention, allows use at larger intervals." Id.

Discussion

The claims are directed to a method of achieving hormone replacement therapy by intermittently (i.e., less often than daily) administering an estrogen

sulfamate, at specified dosages. The examiner rejected the claims for obviousness and for obviousness-type double patenting.

1. Double patenting

The examiner provisionally rejected all of the pending claims under the doctrine of obviousness-type double patenting over claims 23 and 24 of application 09/755,429.

Appellants argue that it would be "premature to determine whether a terminal disclaimer is necessary to overcome the [rejection] as no allowable subject matter has been identified in at least the present application. Applicants plan to address this issue after allowable subject matter is identified." Reply Brief, page 1.

We will affirm the rejection. The practice of making "provisional" double-patenting rejections based on pending applications has been sanctioned by the courts and by this board. See In re Wetterau, 356 F.2d 556, 148 USPQ 499 (CCPA 1966); Ex parte Karol, 8 USPQ2d 1771 (Bd. Pat. App. Int. 1988). Such rejections are proper even when allowable subject matter has not been identified in one, or even both, of the conflicting applications. See, e.g., Karol, 8 USPQ2d at 1773-74 (claims in application on appeal stood rejected for obviousness-type double patenting over claims in copending application; rejection affirmed even though both claims on appeal and claims in copending application also stood rejected for obviousness).

Thus, the rejection is not premature and the propriety of the rejection is an issue in this appeal. In addition, the '429 application has now issued (as U.S. Patent 6,653,298), so the rejection is no longer provisional.

Since the rejection is properly before us and Appellants have not disputed its merits, we affirm it.

2. Obviousness

The examiner also rejected claims 8-17 as obvious in view of Siemann and Gale. The examiner characterized Siemann as "teach[ing] novel estra-1,3,5,(10)-triene amidosulphamates . . . [and] further teach[ing] employing these compounds in compositions and methods for hormone replacement therapy." Examiner's Answer, page 4. The examiner also characterizes Siemann as teaching a dosage of "10 microgram[s] of estradiol, ethinyl-estradiol and estriol per animal per day." Id. The examiner relied on Gale only for its teaching of administering estrogen in combination with a gestagen, a limitation that is relevant only to certain dependent claims. With regard to the "intermittent dosing" limitation of claim 8, the examiner argued that "[i]ntermittent administration instead of daily administration . . . is an optimization of regimen, within the purview of the Skilled Artisan." Examiner's Answer, page 6.

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant." In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A proper § 103 analysis requires "a searching comparison of the claimed

invention – including all its limitations – with the teaching of the prior art." In re Ochiai, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995).

In this case, the examiner has not adequately shown that the prior art would have suggested the method defined by claim 8 to those of ordinary skill in the art. The examiner's rejection has several flaws. First, it relies on a reference that is entirely in German except for an English-language abstract. The abstract does not support the examiner's characterization of the reference.

However, Appellants appear to agree that Siemann "teaches the daily administration of 10 micrograms per day of an estradiol, ethinyl estradiol, and estriol while also disclosing a generic formula that encompasses estriol-3-sulphamate." Appeal Brief, page 3. We will therefore accept the examiner's characterization of the reference.

We nonetheless conclude that Siemann does not support a prima facie case of obviousness, because the examiner has not adequately shown that it suggests the intermittent dosing limitation recited in the claims. According to the examiner, Siemann discloses daily administration, to rats, of 10 µg of an estrogen sulfamate compound. The examiner has not adequately explained how this disclosure would have suggested to those skilled in the art the dosage amounts and schedules recited in claim 8; specifically, 20-300 µg/day every 2-3 days, 0.5-5.0 mg/day every 5-10 days, or 2.0-20 mg/day every 20-40 days.

The examiner's argument—that these dosages are simply "an optimization of regimen"—is not sufficient to support a prima facie case under § 103. It is true that, given a variable that is known to affect the results of a process, disclosure of

an optimal value for that variable is generally not considered nonobvious. See, e.g., In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980).

In this case, however, the examiner has provided no evidence to show that those skilled in the art would have expected that an "optimal" dosage regimen using estrogen-sulfamates in HRT would have included administration less often than once per day. Siemann apparently administered the hormones on a daily basis. Gale, the examiner's secondary reference, discloses "continuous" co-administration of drugs. See column 5, line 8. The instant specification discloses that natural estrogens are quickly eliminated from circulation (page 3), and the examiner has pointed to nothing to show that those skilled in the art would have expected a different result with estrogen-sulfamates.

The examiner has not shown that those skilled in the art would have been led to "optimize" a hormone replacement therapy regimen by administering estrogen sulfamates less often than once per day. Therefore, the examiner has not shown that the claimed method would have been prima facie obvious based on the prior art. The rejection under 35 U.S.C. § 103 is reversed.

Summary

We reverse the rejection under 35 U.S.C. § 103 but affirm the rejection for obviousness-type double patenting.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Sherman D. Winters)
Administrative Patent Judge)
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)
Donald E. Adams) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
) INTERFERENCES
Eric Grimes)
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